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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/192,800

02/07/1994

TETSUJI SUDOH

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06/02/2004

EXAMINER

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/192,800

Applicant(s)

SUDOH ET AL.

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36,37 and 42-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 37 is/are allowed.
- 6) ☒ Claim(s) 42-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42-45 remain rejected under 35 U.S.C. 102(e) as being anticipated by Seilhamer et al [US 5,674,710]. This rejection is maintained for the reasons set forth in the Official Action mailed 12/15/03.

Claims 42-45 remain rejected under 35 U.S.C. 102(e) as being anticipated by Seilhamer et al [US 5,948,761]. This rejection is maintained for the reasons set forth in the Official Action mailed 12/15/03.

Claims 42-45 rejected under 35 U.S.C. 102(e) as being anticipated by Seilhamer et al [US 5,114,923].

Seilhamer et al disclose the instantly claimed peptides at columns 4-5 and 10 and in claims 1-4. It is noted that the peptide of Seilhamer et al claim 4 is the specifically claimed peptide of applicants claim 43 and claim 1 discloses the peptides of all of the rejected claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Seilhamer references above either individually or collectively and claims 46-53 are rejected over Seilhamer et al in view of Landaburu et al [US 4,478,829], Dees et al [US 4,599,227], and Kotitschke et al [US 4,503,039].

The claimed invention is the peptides of claims 42-45 which are rejected above with further limitations of being in the form of a white powder and being in an acid addition salt.

The Seilhamer references are relied on as above and additionally as set forth below. The Seilhamer references are essentially the same in their disclosure and will be treated generically in their teachings. Seilhamer et al have taught the specified peptides of the instantly claimed invention. Seilhamer also have taught that their peptides can be formulated into compositions as neutral or salt forms and disclose a variety of acid

addition salts such as inorganic and organic acids such as tartaric and the like. It has also been taught that the peptides of their invention can be made into a powder form for use in medicinal preparations. See column 17 of '710, column 19 of '923, and columns 17-18 of '396.

Landaburu et al have taught the preparation of a protein in lyophilized form was better suited for use in solution via freeze-drying before lyophilizing.

Kottitschke et al have taught the freeze-drying of a protein for use in medicine, see columns 6-8, for example.

Dees et al have taught the formulation of injectable preparation of a protein. It has been taught that the protein was obtained as a commercially available freeze-dried protein powder (see column 7, for example).

Although Seilhamer et al do not specifically disclose an isolated protein in an acid addition form, Seilhamer et al have clearly taught that their protein can be made into an acid addition salt via inorganic or organic acids such as tartaric acid where these acid addition salts could be used in medicinal preparations.

Although Seilhamer et al have not taught a freeze dried powder or a protein in white powder form it is clear from the disclosure of Seilhamer et al that one in the art could make their protein into a powder form for use as a medicinal, to make, for example an injectable solution of their peptides. The prior art has clearly taught that it was known and routines in the art to make freeze dried samples of medicinal proteins for use in medicinal formulations. It is noted that one in the art would expect that, since the

proteins of Seilhamer and that instantly claimed are the same, the proteins of Seilhamer would be white when freeze dried.

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Claims 36 and 37 are allowed.

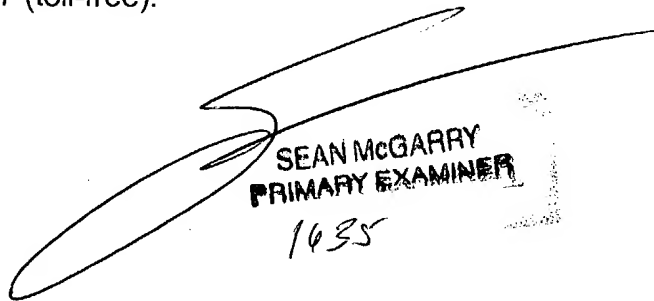
Applicant's arguments filed 3/5/04 have been fully considered but they are not persuasive. Applicants' arguments drawn to the new claims are addressed in the new rejections in the instant Official Action. Applicant has argued that the specific R2 of the invention are not disclosed in the claims of the Seilhamer patents and that the number of peptides to chose from as disclosed in columns 4-5 of the patents is too much to pick and choose from. The argument is not persuasive. Applicant is directed to the newly applied patent and note that the claim indeed recite the same R2 and further the specifically claimed species of claim 4 is the same as that in instant claim 43, for example. The species of peptides in columns 4-5 of all the Seilhamer patents and particularly of the claims the Seilhamer '923 patent which are based one a particular amino acid sequence where, for example, one need only select subsequences of a specific peptide where the core sequence is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SRM



SEAN MCGARRY
PRIMARY EXAMINER
1635